UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MORGANNE MILES, by her mother KRYSTAL MILES; OLIVIA MILES, by her mother KRYSTAL MILES; PASCALE MOSSIN, by her mother AMY MARGARET MCCUTCHIN; THEO CHAN, by his father SUNNY CHAN; LEAH CHAN, by her father, SUNNY CHAN,

Plaintiffs,

v.

MICHAEL O. LEAVITT, Secretary, United States Department of Health and Human Services,

Defendant.

08-CV-0432 (PAC)

ECF CASE

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

During the summer of 2007, New York expanded its State Children's Health Insurance Program (SCHIP), called Child Health Plus (CHPlus), and began offering health insurance coverage to additional uninsured children whose parents could not otherwise afford it.[1] The Plaintiffs are five children whose parents enrolled in the program, paid subsidized premiums of $20 or $40 per child per month, and began obtaining necessary health care. Miles Dec. ¶ 1l; McCutchin Dec. ¶ 14, Chan Dec. ¶ 11.

In an August 17, 2007 Directive, the Defendant announced a new policy for approving SCHIP expansions. *See* Centers for Medicare & Medicaid Services (CMS), *Dear State Health Official* (August 17, 2007) (Directive), at http://www.cms.hhs.gov/smdl/downloads/SHO081707.pdf. In September, Defendant denied New York's SCHIP state plan amendment (SPA) based on the Directive. As a result, Plaintiffs' parents were notified of huge increases in the cost of the coverage for their children: Miles from $20 per month to $196 per month (*id.* ¶ 12); McCutchin from $20 per month to $533 for 3 months (*id.* ¶ 17); Chan from $40 per month per child to $355 per month to cover both children (*id.* ¶ 11). Because of their limited family incomes, Plaintiffs' parents can make these payments only with great difficulty, for example by foregoing other necessities such as groceries or by working jobs whose hours take them away from the children during meal times and bed times *Id.* Yet, the insurance coverage is vital because of Plaintiffs' needs for preventive care and vaccinations and treatment services for conditions such as allergies, surgeries, and emergency care. Miles Dec. ¶¶ 13-18; McCutchin Dec. ¶¶ 19 – 22; Chan Dec. ¶ 13 and 16 – 18. Had the Defendant acted

[1] 42 C.F.R § 457.65 (providing for state plan amendment to take effect on the day specified in the plan amendment).

lawfully pursuant to the Administrative Procedure Act's (APA) required notice-and-comment rulemaking for the August 17 Directive, the provisions of that policy could not have been used to deny the New York SPA and Plaintiffs would have continued to receive health coverage at $20 or $40 per child per month.

Moreover, although the Secretary has represented that, if New York prevails in its appeal of the SPA denial, New York will receive any federal reimbursement previously denied to the State (Def. Mem. at 22, in *New York v. U.S. Dep't of HHS*, 07 Civ. 8621 (PAC)), he makes no similar claim that, if New York prevails, the higher costs of insurance paid each month by Plaintiffs' parents will be refunded. Thus, Plaintiffs are being harmed each month that the Secretary uses illegal rules to deny expansion of New York's SCHIP program.

ARGUMENT

I. SINCE THE SECRETARY'S JURISDICTIONAL ARGUMENTS ARE NOT WELL TAKEN, THE MOTION TO DISMISS SHOULD BE DENIED.

A. The Issue is Ripe for Review, and Plaintiffs Have Standing.

Plaintiffs meet the Article III standing test because, as shown above, they are suffering actual and imminent injury that is fairly traceable to Defendant's August 17 Directive and that is likely to be redressed by a favorable ruling from the Court. *See, e.g.*, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

The Secretary contends, however, that, under the doctrine of prudential ripeness,[2] this case is not ripe because of alleged contingent events. Def. Mem. at 1 n. 1. This

[2] See *Ehrenfeld v. Mahfouz*, 489 F.3d 542, 546 (2d Cir. 2007); *Isaacs v. Bowen*, 865 F.2d 468, 478 (2d Cir. 1989).

contention is in error because it ignores that this case is about the August 17 Directive and its validity under the APA. Unlike the mere proposals raised in *Isaacs*, which rendered the issues "largely hypothetical," 865 F.2d at 478, "this case presents a clear and concrete issue for resolution by a court," *Ehrenfeld*, 489 F.3d at 547, because of the Directive's effect on Plaintiffs' ongoing health coverage.[3]

The Secretary also questions one aspect of constitutional standing, claiming that there is no cognizable injury. Def. Mem. at 1-2. That contention borders on the disingenuous. Plaintiffs' injury is the loss of either health care or financial security. *See supra* at 1-2. As a result of the CMS policy, they have been deprived of access to health care and/or to affordable health care, leaving as their only alternative to purchase insurance out of funds that they need for the necessities of life.

Third, the Secretary argues that prudential standing concerns should bar Plaintiffs' suit, on the ground that New York is better situated to bring a challenge to the denial of its state plan amendment. Def. Mem. at 2. But, again, this case is about the propriety of the August 17 Directive under the APA. Furthermore, the Secretary offers no authority to support his contention that the Plaintiffs' case is barred because their claims are somehow protected by or derivative of the State's. *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 99-100 (1979) and *N.Y. State NOW v. Terry*, 886 F.2d 1339, 1346 (2d Cir. 1989) only require that plaintiffs assert injuries to a distinct group, which Plaintiffs have certainly done. And, *U.S. v. Hooker Chem. & Plastics Corp.*, 749

[3] The Memorandum of Law in Support of Defendant's Motion to Dismiss in *New York v. U.S. Dep't of HHS*, 07 Civ. 8621 (PAC), argues that the case is not ripe for review because reconsideration of New York's SPA is pending. That coincidental proceeding is not relevant to the Plaintiffs' case here, which involves the straightforward question of whether the Defendant's issuance of the August 17 Directive violated the APA and the SCHIP statute.

F.2d 968, 984-985 (2d Cir. 1984) and *Access 4 All, Inc. v. Trump Int'l Hotel & Tower Condominium*, 458 F. Supp. 2d 160, 175 (S.D.N.Y. 2006) are concerned with intervention and associational standing respectively, not prudential standing. *See Ass'n of Data Processing Serv. Org. v. Camp*, 397 U.S. 150, 151 (1970) ("Generalizations about standing to sue are largely worthless as such.").

The contention that prudential standing should preclude beneficiaries from challenging a policy that will deprive them of eligibility and health coverage has no support in logic or the case law and is contrary to the standing tests that govern the APA. *See, e.g., Abbott Labs. v. Gardner*, 387 U.S. 136, 141 (noting the presumption that the APA's "generous review provisions" should receive a "hospitable interpretation").

B. Review is Not Precluded by the SCHIP Statute.

Relying on *Block v. Community Nutrition Institute*, 467 U.S. 340 (1984), the Secretary argues that Plaintiffs' suit is precluded by the SCHIP statute. Def. Mem. at 3-5. His position, however, is at odds with the legislative history of the APA, controlling case law, and the SCHIP statutory scheme.

The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action ..., is entitled to judicial review thereof." 5 U.S.C. § 702. Congress intends the APA to have a broad remedial purpose:

> To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.

Ass'n of Data Processing Serv. Org., 397 U.S. at 156-57 (citing 5 U.S.C. § 701(a) and quoting H.R. Rep. No. 1980, 79th Cong., 2d Sess., 41).

In *Ass'n of Data Processing*, the Supreme Court emphasized the APA's "generous review provisions" and held that the Act should be construed "not grudgingly but as serving a broadly remedial purpose." 397 U.S. at 156. Accordingly, the Court allowed the data processors to proceed with their case even though the underlying National Bank Act had no reference to aggrieved persons and no review provision. *Id.* at 157 (finding that intent to preclude was not "fairly discernible in the statutory scheme"); *see also Clarke v. Securities Indus. Ass'n*, 479 U.S. 388, 395 (1987) (reiterating the holding in *Ass'n of Data Processing*).

Community Nutrition Institute affirms the presumption in favor of judicial review of agency action. 467 U.S. at 349. The presumption can be overcome only by "clear and convincing evidence" that Congress intended to preclude review. *Id.* at 350-51. The intent to preclude must be "fairly discernible" from the detail of the legislative scheme. *Id.* at 351 (quoting *Ass'n of Data Processing*, 397 U.S. at 157). The presumption favoring judicial review "is controlling" where "substantial doubt about the congressional intent exists." *Id.*; *see also*, *e.g.*, *Natural Resources Defense Council v. Johnson*, 461 F.3d 164, 171-172 (2d Cir. 2006). Thus, *Community Nutrition Institute* is fully consistent with the Court's broad approach to standing, and "the reasoning process the Court used … will yield holdings that injured plaintiffs have standing in a high proportion of cases." Richard J. Pierce, Jr., III *Admin. L. Treatise* (4th ed.), § 16.9 at 1191.

Here, the relevant statute is the SCHIP statute. The Secretary acknowledges that the "purpose of the SCHIP statute is to provide insurance to low-income children," Def.

Mem. at 4.[4] However, he argues that the state plan review provisions of another statute, 42 U.S.C. § 1316, evidence the requisite congressional intent to preclude the Plaintiffs' case. The vastly different structures of the SCHIP statutory scheme and that in *Community Nutrition Institute* pose insurmountable problems for this argument.

In *Community Nutrition Institute*, milk consumers sought judicial review of a milk marketing order issued by the Department of Agriculture (DOA) under the Agricultural Marketing Agreement Act (AMAA). 467 U.S. at 341. The AMAA contains an elaborate scheme for the DOA and milk producers and handlers to set milk prices and for administrative and judicial review if there are disputes. For example, before the DOA can finalize a price order, it must disseminate the proposal to milk handlers and producers and obtain agreement from 50% of handlers or two-thirds of producers. Milk handlers who object to the order can obtain judicial review after exhausting formal administrative remedies. *See* 467 U.S. at 342, 346 (discussing 7 U.S.C. § 608c). Because milk consumers were not mentioned in this "complex and delicate" scheme, the Court concluded that Congress intended to exclude them from obtaining judicial review of milk price orders. *Id.* at 348.

Significantly, the *Community Nutrition Institute* Court also acknowledged the purpose of the AMAA to establish a "cooperative venture among the Secretary, handlers, and producers the principal purposes of which are to raise the price of agricultural

[4] *See also Julia M. v. Scott*, 498 F. Supp. 2d 1245, 1246 (W.D. Mo. 2007) (stating that SCHIP "provides health assistance to uninsured, low income children whose family income is above the State's Medicaid income limits, but who cannot afford private health insurance"), *same case*, 243 F.R.D. 365, 366 (W.D. Mo. 2007) (noting that Missouri's SCHIP covers parents of uninsured children with incomes from 151-300% of the federal poverty level who do not have access to affordable health care coverage).

products. . . ." *Id.* at 346; s*ee also id.* at 342 (quoting legislative history stating that the purpose of the AMAA is "to raise producer prices"). In short, "the statute creates a classic government-sponsored cartel, the inevitable effect of which always is to injure consumers by artificially increasing producer prices." Richard J. Pierce, Jr., III *Admin. L. Treatise* (4th ed.), § 16.9 at 1192. The purpose of the AMAA is to legitimize the heightened milk prices agreed to by the cartel. It is not at all surprising, then, that milk consumers were held unable to enforce the AMAA.

In contrast to the purpose of the AMAA and the "detailed mechanism for judicial consideration" contained in that statute, 467 U.S. at 349, the SCHIP statute does not address judicial review at all—for the State, health care providers, or beneficiaries. *See* 42 U.S.C. §§ 1397-1397jj. That makes this case more analogous to *Ass'n of Data Processors*. Moreover, the provision upon which the Secretary relies relates to appeal of state plan denials, which—to repeat—is not the issue raised by Plaintiffs' Complaint. *See* 42 U.S.C. § 1316(a).

The SCHIP statutory scheme, taken as a whole, also does not evidence clear and discernible congressional intent to preclude Plaintiffs' APA case. According to the legislative history, the purpose of title XXI is "to provide States with the tools they need to effectively … expand … coverage to low-income uninsured children in a manner that will increase their access to and use of quality primary and preventive care." H.R. Rep. No.105-149, at 603 (1997), *reprinted in* 1997 WL 353017. The SCHIP statute requires participating States to make a range of basic health care services available to children, including inpatient and outpatient hospital care, physician's services, laboratory and x-ray services, and preventive care. 42 U.S.C. § 1397cc(c). States are required to reach out to

potentially eligible families and inform them of SCHIP and assist them in enrolling their children. *See id.,* § 1397bb(c). The cost sharing, if any, that the State chooses to impose on enrollees must be limited based on family income, and certain services must be excluded from cost sharing. *See id.*, § 1397cc(e).

In short, the SCHIP statutory scheme exists to benefit children—those who, like Plaintiffs, need SCHIP coverage so that they can gain access to affordable, quality health care. This case does not present a situation in which allowing Plaintiffs' suit to go forward will "severely disrupt [a] complex and delicate administrative scheme." *Community Nutrition Institute*, 467 U.S. at 348. There is no indication that Congress intended to bar injured children and their families from obtaining judicial review of adverse agency action pursuant to the APA.[5]

II. SINCE THE AUGUST 17, 2007 DIRECTIVE VIOLATED THE APA, THE PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT SHOULD BE GRANTED.

Under Fed. R. Civ. P. Rule 56(c), a motion for summary judgment must be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Here, there are no

[5] Similarly, in *Banks v. Sec'y of Indiana Family & Social Services Admin.*, 997 F.2d 231, 238-239 (7th Cir. 1993), the court allowed an APA challenge involving the Medicaid Act by an eligible recipient and a family member liable for the medical bills. Like the SCHIP statute, Medicaid makes federal funds available to States that submit State plans. *Compare* 42 U.S.C. §§ 1396-1396v *with* 42 U.S.C. §§ 1397-1397ff. The Secretary argues here that Plaintiffs lack standing to bring an APA challenge because § 1397bb contains a nonentitlement provision. However, as *Banks* illustrates, the question of whether the plaintiff in an APA suit is entitled to the benefits offered by the statute is not relevant. *See* 997 F.2d at 239.

disputed issues of fact, and the question is a purely legal one: whether the issuance of the August 17 Directive violates the Administrative Procedure Act.

A. Provisions of the August 17 Directive were Beyond the Authority of the Federal Agency and Therefore are Invalid.

The SCHIP statute authorizes the Secretary of Health and Human Services to make and publish rules and regulations that are not inconsistent with the Act. *See* 42 U.S.C. § 1302(a). However, "[t]he right to alter, amend, or repeal any provision of this Act is . . . reserved to the Congress." *Id.* at § 1304. This case challenges provisions of the August 17 Directive as invalid because they are contrary to the SCHIP statute.

To determine claims such as this, the court proceeds in two steps. First, the agency rule is compared to the statute's charge. "If Congress has 'directly spoken to the precise question at issue' and 'the intent of Congress is clear, that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" *Waterkeeper Alliance v. EPA*, 399 F.3d 486, 497 (2d Cir. 2005) (quoting *Chevron USA, Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984)). Standard tools of statutory construction are used to make this determination. *See Riverkeeper, Inc. v. EPA*, 358 F.3d 174, 184 (2d Cir. 2004). If, however, the statute is silent or ambiguous, then the court moves to the second step and considers whether the agency's rule is based on a permissible construction of the statute. *See Waterkeeper*, 399 F.3d at 497 (quoting *Chevron*, 467 U.S. at 843).

Furthermore, because there is a claim under the APA of arbitrary, capricious or abusive action by the agency, the court also asks "whether the agency 'has examine[d] the relevant data and articulate[d] a satisfactory explanation for its action….'" *Id.* at 498

(quoting *Motor Vehicle Mfr. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)). The court will normally deem invalid an agency rule where

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id. (quoting *Motor Vehicle Mfr.*, 463 U.S. at 43).

1. The Cost Sharing Requirement

In the August 17 Directive, Defendant announced a new, mandatory cost sharing requirement affecting SCHIP enrollees. States expanding their SCHIPs to children in families with income levels above 250% of the federal poverty level (FPL) are required to "impose cost sharing in approximation to the cost of private coverage," and

> [t]he cost sharing requirement under the State plan compared to the cost sharing required by competing private plans must not be more favorable to the public plan by more than one percent of the family income, unless the public plan's cost sharing is set at the five percent family cap.

Centers for Medicare & Medicaid Services, *Dear State Health Official* (Aug. 17, 2007). Statement of Undisputed Facts, Exhibit A.

The Directive's mandatory cost sharing requirement is in direct conflict with the SCHIP Act. The Act requires that

> [a] State child health plan shall include a description, consistent with this subsection, of the amount *(if any)* of premiums, deductibles, coinsurance, and other cost sharing imposed. *Any such charges* shall be imposed pursuant to a public schedule. . . .
>
> For children not described in subparagraph (a) [children in families with income below 150% of the FPL] . . ., *any* premiums, deductibles, cost sharing or similar charges imposed under the State child health plan may be imposed on a sliding scale related to income, except that the total annual aggregate cost-sharing with respect to all targeted low-income children in a family under this subchapter may not exceed 5 percent of such family's income for the year involved.

42 U.S.C. §§ 1397cc(e)(1)(A), (3)(B) (emphasis added). Congress' use in the provision of the permissive word "may" and its reference to "any such charges" contrast with its use of the mandatory word "shall" to require the State to include a description of any such charges it might decide to impose. Clearly, the statute permits, but does not require, States to impose cost sharing on beneficiaries. *See Weinstein v. Albright*, 261 F.3d 127, 137 (2d Cir. 2001) ("[W]hen the same [statute] uses both 'may' and 'shall', the normal inference is that each is used in its usual sense -- the one act being permissive, the other mandatory.") (quoting *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947)).

The legislative history of the provision shows that Congress meant to leave the decision of whether to impose cost sharing to the States:

> The conference agreement would require that state child health plans include descriptions of the amount, *if any*, of premiums, deductibles, coinsurance, and other cost sharing imposed. Any cost sharing imposed must be pursuant to a public schedule.… For targeted low-income children in families with income above 150% of the poverty line, premiums, deductibles, cost sharing or similar charges may be imposed on a sliding scale related to income only insofar as the total annual cost sharing for all targeted low-income children in a family does not exceed 5% of such family's income.

H.R. Conf. Rep. No.105-217, at 903 (1997), *as reprinted in* 1997 U.S.C.C.A.N. 176, 524 (emphasis added).

The promulgated regulations also address this issue and, prior to the issuance of the August 17 Directive, were consistent with the statute and congressional intent, stating as follows:

> *When a State imposes premiums, enrollment fees, or similar fees on enrollees*, the State plan must describe—(a) The amount of the premium, enrollment fee, or similar fee imposed on enrollees; (b) The time period for which the charge is imposed; (c) The group or groups that are subject to the premiums, enrollment fees, or similar changes; (d) The consequences for an enrollee or applicant who does not pay a charge,…; and (e) The methodology used to ensure that total cost-sharing liability for

> a family does not exceed the cumulative cost-sharing maximum specified in § 457.560.

42 C.F.R. § 457.510 (emphasis added).

In sum, the cost sharing requirement violates the plain words of title XXI, the stated congressional intent behind the provision, and the agency's own currently promulgated regulations. As such, the requirement is invalid and unenforceable.

In addition, as noted above (*supra* at 9), a court must also ask "whether the agency 'has examine[d] the relevant data and articulate[d] a satisfactory explanation for its action….'" *Waterkeeper*, 399 F.3d at 498 (quoting *Motor Vehicle Mfr. Ass'n*, 463 U.S. at 42). The August 17 Directive includes no analysis or data to support the introduction of the mandatory cost sharing requirement. The requirement is therefore an invalid rule under APA analysis as well.

2. The 95 Percent Enrollment Requirement

Before extending coverage to children with family incomes over 250% of the FPL, the August 17 Directive also requires States to "enroll at least 95 percent of the children in the State below 200 percent of FPL who are eligible for either SCHIP or Medicaid." Directive at 2. Like the cost sharing requirement discussed above, the 95% enrollment requirement violates the plain words of the SCHIP statute. The statute provides:

> The [State SCHIP] plan shall include a description of the eligibility standards used to determine the eligibility of targeted low-income children for the child health assistance plan. Such standards *may* include (to the extent consistent with this subchapter) those relating to … income and resources, … access to or coverage under other health coverage, and duration of eligibility.

42 U.S.C. § 1397bb(b)(1)(A) (emphasis added).

> Such eligibility standards . . . shall, within any defined group of *covered* targeted low-income children, not *cover* such children with higher family income without *covering* children with a lower family income….

Id. at § 1397bb(b)(1)(B)(i) (emphasis added).

> The plan shall include a description of procedures to be used to ensure (A) through both intake and followup screening, that only targeted low income children are furnished children health assistance under the State child health plan; (B) that children found through the screening to be eligible for medical assistance under the State Medicaid plan . . . are *enrolled* for such assistance under such plan ….

Id. at § 1397bb(b)(3) (emphasis added).

Under the rules of statutory construction, Congress' choice of words must be given controlling authority. In this provision, § 1397bb(b), Congress unambiguously gave to the States the flexibility to decide whether to include as an eligibility standard a standard that looks at a child's access to other health coverage. *See id.* at § 1397bb(b)(1)(A) (State plan eligibility standards "may" include access to or coverage under other health coverage). For States opting to include such a standard, the SCHIP statute directs the States and the Secretary to "cover" lower income children first—that is, make them eligible to participate in the program. In addition, the States must have intake and follow-up screening procedures to identify whether children in families who decide to take up the SCHIP coverage are actually eligible for Medicaid and, if so, to "enroll" those children into the Medicaid program. *Compare id.* § 1397bb(b)(1)(B)(i) *with id.* at § 1397bb(b)(3). Thus, while States have the option whether to include eligibility standards that concern other health coverage, once a State elects that option the specific requirements of the statute control. The requirements of the Secretary are inconsistent with the language of the provision and, thus, invalid.

The plain language of the statute is supported by the legislative history. *See* H.R. Conf. Rep. 105-217, at 900 (1997), *as reprinted in* 1997 U.S.C.C.A.N. 176, 521 (giving States flexibility in setting eligibility standards and, stating, that these "standards could include . . . access to other health insurance"); H.R. Rep. 105-149, at 613 (1997), *reprinted in* 1997 WL 353017 (discussing descriptions needed in State child health plan in terms of "covering children with lower family incomes" before expanding coverage to higher income children and calling for procedures to ensure that "children found through screening to be eligible for medical assistance under the State's Medicaid program [are] enrolled in Medicaid"). The promulgated regulations address this issue and, prior to the issuance of the August 17 Directive, were consistent with the statute's distinction between "covering" lower income children before expanding and actually "enrolling" children into the Medicaid program through screening. *See* 42 C.F.R. **§** 457.320(b) (regarding covering lower income children); *id.* at § 457.350 (regarding Medicaid enrollment).

Furthermore, as with the new cost sharing requirement, the August 17 Directive includes no analysis or data whatsoever to support the introduction of the new 95% enrollment requirement. *See Waterkeeper*, 399 F.3d at 498. It is therefore invalid under APA review as well.

B. The August 17 Directive was Not Promulgated in Accordance With the Rulemaking Requirements of 5 U.S.C. § 553 and Therefore is Invalid.

Even it were determined that the Defendant's actions in issuing the August 17 Directive did not violate either the SCHIP statute or 5 U.S.C. § 706(2)(A), his failure to follow the notice-and-comment requirements of 5 U.S.C. § 553(b) in promulgating the

Directive renders it invalid. The Second Circuit has recently reiterated the purpose and importance of the rulemaking requirement:

> We have previously stated that "[n]otice is said not only to improve the quality of rulemaking through exposure of a proposed rule to comment, but also to provide fairness to interested parties and to enhance judicial review by the development of a record through the commentary process." *National Black Media Coalition v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986).

Riverkeeper, Inc. v. U.S.E.P.A., 475 F.3d 83, 112-13 (2d Cir. 2007), cert. gr., --- S.Ct. ---, 2008 WL 1699464, 1699465, 1699466 (Nos. 07-588, -589, -597, April 14, 2008). Although there is an exception to the requirement of notice-and-comment rulemaking for "interpretative" (or interpretive) provisions, 5 U.S.C. § 553(b)(A), the policies reflected in the Directive are not interpretive. Even if they were so deemed, the Secretary's change from his previous interpretation requires compliance with § 553.

Unlike interpretive rules, "[l]egislative rules bind members of the agency and the public," *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000), and "create new law, rights, or duties …." *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993). Interpretive rules, by contrast, merely clarify existing law. *See, e.g., Zhang v. Slattery*, 55 F.3d 732, 745 (2d Cir. 1995). A legislative rule (formerly referred to as a "substantive rule," *see id.* at 745 n. 8),

> grants rights, imposes obligations, or produces other significant effects on private interests, while an interpretive rule is an agency's intended course of action, its tentative view of the meaning of a particular statutory term, or internal housekeeping measures organizing agency activities.

White, 7 F.3d at 303 (internal quotation marks and citations omitted). Furthermore, the Second Circuit has adopted a D.C. Circuit analysis under which a rule is legislative if it meets any of four factors, one of which is "whether the rule effectively amends a prior

legislative rule." *Sweet*, 235 F.3d at 91 (quoting *American Mining Congress v. Mine Safety & Health Administration*, 995 F.2d 1106, 1112 (D.C.Cir. 1993)).

The August 17 Directive is legislative as it has imposed new obligations on the States and therefore precluded those who would have been eligible under New York's SCHIP program from receiving the benefits of that program. Thus, under the Directive, for the first time a State that seeks to enroll beneficiaries in families with incomes over 250% of the federal poverty level must first:

(1) demonstrate that the State has enrolled at least 95% of the children in the State below 200% of FPL in either the SCHIP or Medicaid programs;

(2) demonstrate that the number of children ensured through private employers has not decreased by more than 2% in the last five years;

(3) implement a cost sharing plan by which the cost sharing for the public plan must not be more favorable to competing private plans by more than 1% of family income (unless the public's plan cost sharing imposes a 5% family cap);

(4) institute a minimum one-year waiting period before SCHIP coverage is available, with no exceptions for such developments as a loss of private coverage or change of jobs with no dependent coverage; and

(5) satisfy a monthly reporting requirement on data relating to crowd-out.

The Directive claims that these and other new obligations are mere clarifications of the regulatory provision for States to describe "reasonable procedures" to prevent crowd-out of private coverage.[6]

[6] These requirements of the Directive conflict with 42 C.F.R. § 457.805, which provides: "The State plan must include a description of reasonable procedures to ensure

In fact, though, through the August 17 Directive, the Secretary has imposed strict and specific demands on States for their SCHIP programs where previously the States were merely describing the "reasonable procedures" that they would undertake. As the D.C. Circuit has noted in a similar context:

> The distinction between an interpretative and substantive rule more likely turns on how tightly the agency's interpretation is drawn linguistically from the actual language of the statute or rule. If the statute or rule to be interpreted is itself very general, using terms like "equitable" or "fair," and the "interpretation" really provides all the guidance, then the latter will more likely be a substantive regulation.

Paralyzed Veterans of America v. D.C. Arena L.P., 117 F.3d 579, 588 (D.C.Cir. 1997) (citations omitted). Moreover, in addition to providing specific requirements to replace the generalities of "reasonable procedures," the Directive's uncompromising minimum one-year waiting period requirement ignores and directly contradicts the specific provisions of a companion regulation that establishes a six-month waiting period and that permits exceptions even to that. *See* 42 C.F.R. § 457.810(a)(1), (2).

This imposition of new obligations and duties defines the Directive as a legislative rule and created a legislative basis for agency action against States. *See*, *e.g.*, *Sweet*, 235 F.3d at 94 (regulations promulgated pursuant to statute "created enforceable disclosure requirements on the regulated community"). That this is the effect of the Directive is demonstrated by the defendant Secretary's refusal to approve New York's SPA. In that September 7, 2007 determination, the Secretary cited the State's failure to meet the 95%-enrollment criterion, the one-year waiting period requirement, and the cost-sharing obligation as his grounds for disapproving the SPA. Prior to the existence of

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that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans as defined at § 457.10."

the August 17 Directive, none of these requirements existed, and there was no authority for the Secretary to take this action. The Directive provided the basis for the adverse action against the State. Promulgation of the terms set out in the Directive was therefore legislative, as it "effectively amend[ed] a prior legislative rule," *Sweet*, 235 F.3d at 91, that is, the regulations that were the result of notice-and-comment rulemaking and that previously had established the standards for SPAs.

Even if the Directive is not considered legislative, however, the changes that it wrought in the relevant rules required the agency to engage in rulemaking. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 100 (1995), the Supreme Court concluded that the agency manual provision there at issue ("PRM § 233") was interpretive and therefore would not normally require rulemaking, but added: "We can agree that APA rulemaking would still be required if PRM § 233 adopted a new position inconsistent with any of the Secretary's existing regulations." Thus, regardless of a rule's designation as interpretive or legislative, if it has the effect of taking a new position from that in the regulation, the agency must engage in rulemaking.

The Second Circuit relied on *Guernsey Memorial* when it recently stated the law in these terms: "An agency may modify a regulation that has already been promulgated, therefore, only through the process of notice and comment rulemaking." *Riverkeeper*, 475 F.3d at 117. The *Riverkeeper* decision also relies on a D.C. Circuit case, which analyzes the need for rulemaking in these terms:

> Rule making, as defined in the APA, includes not only the agency's process of formulating a rule, but also the agency's process of modifying a rule. When an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment .... [A] modification of an interpretive rule construing an

> agency's substantive regulation will ... likely require a notice and comment procedure.

Alaska Professional Hunters Ass'n, Inc. v. FAA, 177 F.3d 1030, 1034 (D.C.Cir. 1999) (citations and internal quotation marks omitted); *see also Paralyzed Veterans*, 117 F.3d at 586 ("To allow an agency to make a fundamental change in its interpretation of a substantive regulation without notice and comment obviously would undermine those APA requirements.").

In the instant situation, far from just clarifying its rule, the agency has made "a fundamental change in its interpretation" of the regulations. As the Directive points out, the Secretary had previously accepted one or more of five State-created "crowd-out strategies" to satisfy the "reasonable procedures" language of the regulations. These were consistent with the agency's direction to the States to develop strategies to prevent substitution, rather than having the federal agency dictate the terms.[7]

By contrast, via the Directive, the agency now has taken the opposite tack, as it demands that States satisfy discrete, specific, and onerous obligations (see *supra* at 15-16). As a consequence, SPAs that had previously been approved by the Secretary are now being disapproved. This differential resolution results solely from the fact that the agency has changed its interpretation of the regulations.

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[7] In the preamble to the proposed rules, the then-Secretary stated that she would not "prescribe a particular strategy, but will evaluate each State's strategy separately." 64 F.R. 60882, 60922 (Nov. 8, 1999). She also noted that the agency had considered "requir[ing] a set of specific procedures that each State would have to use to address substitution. We rejected this option because the statute authorizes States to design approaches to prevent substitution, not the Federal government." *Id*.; *see also* 66 F.R. 2490, 2493 (Jan. 11, 2001) (preamble to final regulations simply notes that "[a]bove 250 percent of the FPL, States must have a substitution prevention mechanism in place, however we encourage States to use other strategies than waiting periods.").

The August 17 Directive is a legislative rule and therefore demands that the Secretary comply with the notice-and-comment requirements of 5 U.S.C. § 553(b). Even if it is considered interpretive, however, the agency still had to satisfy the APA's rulemaking requirements because the Directive represented a significant change in its interpretation of the regulations. Accordingly, since the Directive was published without the benefit of rulemaking, it is invalid and unenforceable.

CONCLUSION

For the foregoing reasons and based upon the well-pled allegations of the Plaintiffs' Complaint, the Secretary's Motion to Dismiss should be denied, and Plaintiffs' Motion for Summary Judgment should be granted.

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Respectfully submitted,

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